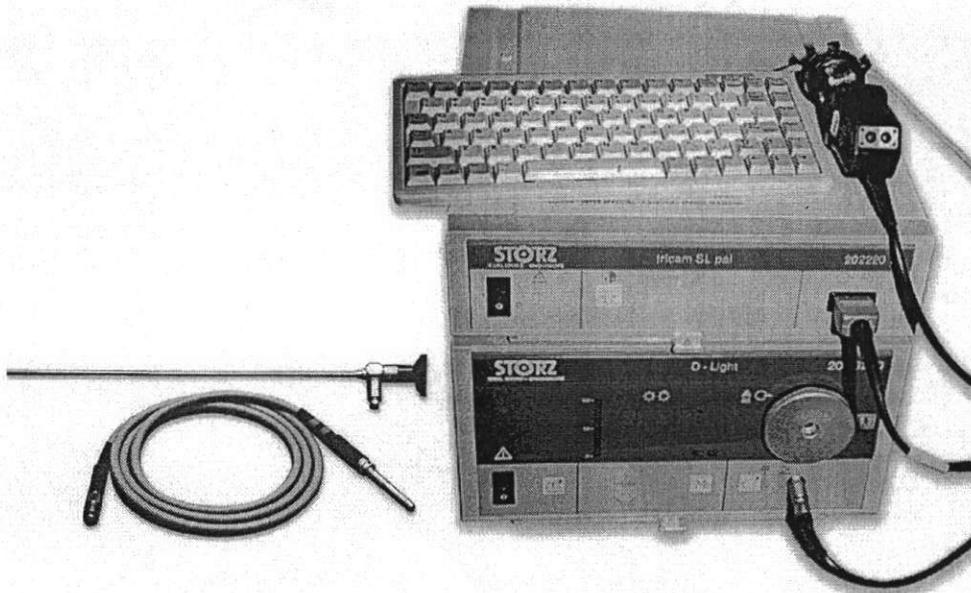


Instruction Manual



STORZ
KARL STORZ—ENDOSKOPE

Photodynamic Diagnostic
D-Light C (PDD) System

Important information for the users of KARL STORZ instruments

Thank you for placing your confidence in the name of KARL STORZ. As with all of our products, this product is the result of years of experience and great care in manufacture. You and your organization have decided in favor of a modern high quality piece of equipment from KARL STORZ.

This instruction manual is intended to serve as an aid in the proper cleaning, sterilization and operation of the D-Light C (PDD) Photodynamic Diagnostic System. All essential details of the components and all actions required on your part are clearly presented and explained. We ask that you read this manual carefully before proceeding to work with the system. Insert this manual in its protective binder and keep it available for ready reference in a convenient and conspicuous location near the equipment.

If you have any questions, please call Technical Support at Karl Storz Endoscopy - America, Inc. (800) 421-0837.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

General Warning

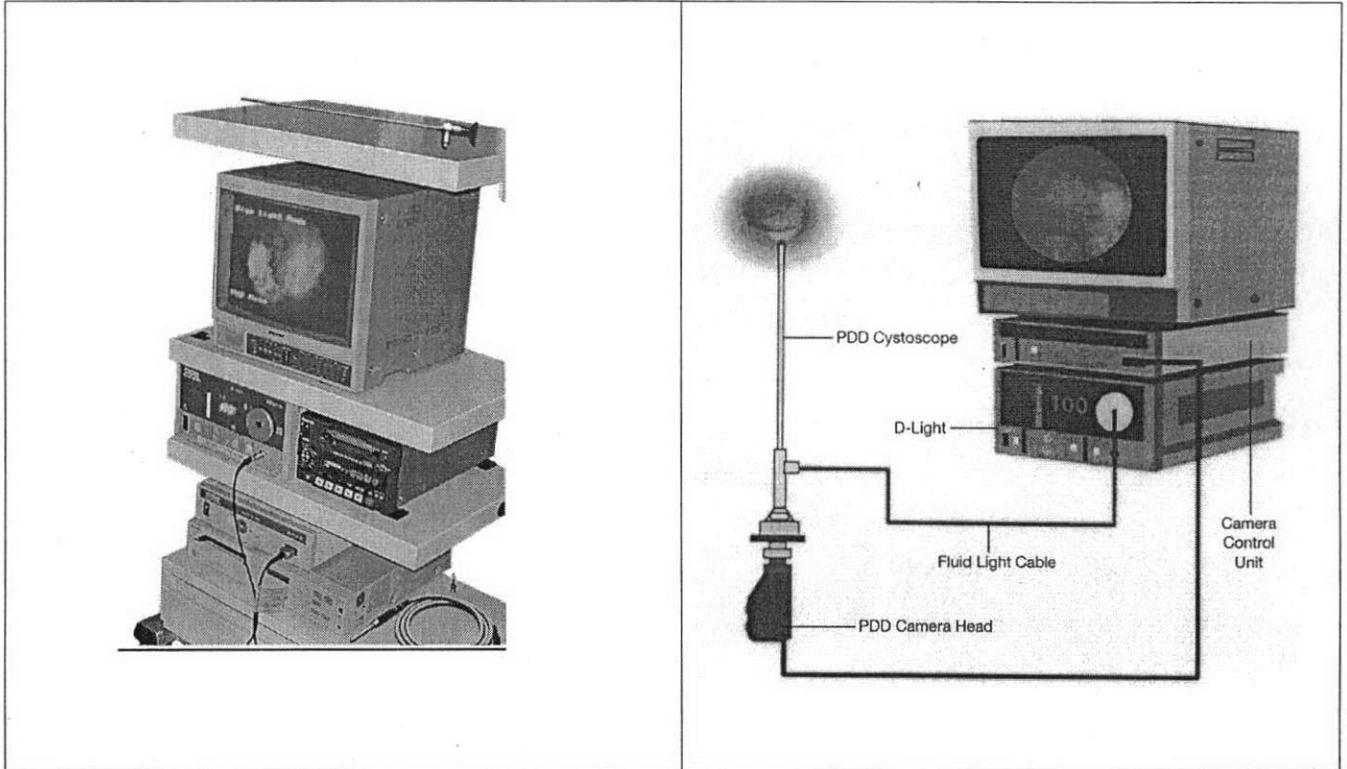
The user of the KARL STORZ PDD System should be thoroughly trained in its use and the applicable medical procedures. Use of this instrument should not be undertaken until the user has fully familiarized himself/herself with the instructions for use, assembly, and care. Instruction manuals should be carefully studied and available to the endoscopic team during the procedure; it is essential to follow the instructions contained in the instruction manual, with particular attention to the cautions and warnings.

Care must be exercised during endoscopic procedures. The instruments may be broken and the surrounding tissue may be damaged. Possible injuries may include perforation, infection, and electrical or thermal burns.

Symbols Employed

-  Read the instructions carefully before operating the equipment
-  Power On
-  Power Off
-  Standby mode
-  Video-controlled brightness setting
-  Manual brightness setting
-  Blue light operating mode
-  Light exit
-  Lamp brightness
-  Footswitch connector
-  Lamp warning operating time (350 hours)
-  Replace lamp (operating time 400 hours)
-  Grounding terminal
-  Protective Earth (ground)
-  Alternating Current
-  White Balance
-  Receptacle for camera head cable connector
-  Applied part of type BF
-  **WARNING: Risk of explosion if used in the presence of flammable anesthetics.**
-  **WARNING: To reduce the risk of electrical shock, do not remove cover. Refer servicing to qualified service personnel.**
Keep out of reach of patients.
Do not store liquids on or above the unit.

Illustrated Description



Components of the D-Light C PDD System

Components:

Specifications:

| | | | | | |
|--|-------------------------|--------------------------|-------------------------|-----------------|-----------------|
| 1) PDD Telescopes | Model Number: | 27005AIA | 27005FIA | 27005BIA | 27005CIA |
| | Working Shaft diameter: | 4.0 mm | 4.0 mm | 4.0 mm | 4.0 mm |
| | Working Shaft length: | 30 cm | 30cm | 30 cm | 30 cm |
| | Viewing Angle | 0° | 12° | 30° | 70° |
| 2) D-Light-C light source 201336 20 | Lamp type | 300 W Cermax® Lamp | | | |
| | Dimensions | 300 mm X 164 mm 320 mm | | | |
| | Weight | Approx. 11 kg | | | |
| 3) PDD camera head | | Telecam® 2021237 | Tricam® 20221137 | | |
| | | Urocam® 101212138 | | | |
| | Minimum sensitivity- WL | 2 lux | 2 lux | | |
| | Weight | 178 g | 240 g | | |
| 4) Camera control unit | | Telecam® SL-PDD | Tricam® SL-PDD | | |
| | | 202120 020-120 | 20222120 020-1 | | |
| | Image sensor | ½" CCD-chip | 3 x ½" CCD-chip | | |
| | Picture sensor | 6.4 mm x 4.8 mm | 6.4 mm x 4.8 mm | | |

Abbreviations Used

PDD = photodynamic diagnostics

WL = white light

BL = blue light

CCU = camera control unit

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General Information for the Safe Use of the PDD System

User qualifications

The KARL STORZ PDD System is restricted to use only by physicians who have completed appropriate training in rigid cystoscopy, and who have been trained in the use of the KARL STORZ PDD System and the drug Cysview® (hexaminolevulinate hydrochloride) for Intravesical Solution. The physician should use his/her judgment and experience in interpreting the fluorescence images

Warnings and precautions

Please read this manual carefully. It is very important that the user be thoroughly familiar with the operation of the instrument prior to use on a patient. The terms "Warning", "Caution" and "Note" are intended to draw your attention to important parts of the instruction manual. All warnings, precautions and notes should be thoroughly reviewed prior to use of the instrument. Close attention to all warnings, precautions and notes is necessary for safe and effective operation of the device.

Definitions

WARNING: A warning indicates that the personal safety of the patient or physician may be compromised. Disregarding the warning may result in serious injury to the patient or the physician.

Caution: A caution indicates that the device may be damaged if the caution is disregarded.

Note: A note provides additional information regarding the safe operation of the instrument.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

General Information for the Safe Use of the PDD System

Indication for Use

The Karl Storz Photodynamic Diagnostic D-Light C (PDD) system in combination with the optical imaging drug Cysview® (hexaminolevulinate hydrochloride) for Intravesical Solution is indicated for photodynamic blue light cystoscopy, as an adjunct to white light cystoscopy for the detection of non-muscle invasive papillary cancer of the bladder in patients suspected or known to have the lesion on the basis of a prior cystoscopy.

Description of D-Light C PDD System

The D-Light C PDD System consists of a D-Light-C light source, specific PDD telescopes for cystoscopy, the Telecam® SL/ Tricam® SL cameras, PDD camera head, and fluid light cables. The system has three modes of operation an attenuated white light (WL) mode (Mode 1) for use during fluorescence examinations, a PDD or blue light (Mode 2) mode for identification of fluorescent images, and a high intensity white light mode (Mode 3) for normal endoscopic examinations when the PDD system is not in use.

Caution: Unauthorized conversions or modifications of the device will VOID the warranty.

Safety warnings when using the D-Light C PDD SYSTEM and Cysview

WARNING Cysview® Contraindications for Use: The physician should refer to the Cysview (hexaminolevulinate hydrochloride) for Intravesical Solution Package Insert contraindications before selecting patients to receive Cysview and to identify the Cysview full prescribing information.

WARNING The D-Light C PDD system must be used in combination with the drug Cysview® (Photocure) as an adjunct to white light to view tissue specific fluorescent images. If the drug is not used fluorescent images will not be present. The D-Light C blue light mode is not indicated as a stand-alone product.

WARNING The safety and effectiveness of use of the D-Light C PDD System in combination with Cysview in pediatric patients has not been established.

WARNING: The physician should first perform a complete cystoscopy examination in white light mode (Mode 1), switch light modes, and then repeat the examination in the PDD or blue light (Mode 2) fluorescence mode. Biopsy procedures should be performed only after completing both examinations. The physician should biopsy all abnormal areas that are identified in either WL or PDD mode.

WARNING Do not use the KARL STORZ D-Light-C PDD System to determine the histology of tissue. The fluorescent images may also result from inflammation, scope trauma, scar tissue, the presence of immunotherapy or chemo-preventive agents. Images that appear negative may not always accurately indicate the absence of abnormal tissues, i.e., not all abnormal bladder tissue will be detected.

WARNING False-positive and false-negative results may occur with the PDD assisted tissue characterization after treatment with Cysview®. The PDD System is only to be used as an adjunct to white light (WL) cystoscopy. Use other methods, such as histological review, for validation.



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WARNING: The KARL STORZ D-Light-C PDD System is restricted to use only by physicians who have completed appropriate training in rigid cystoscopy, and who have been trained in the use of the KARL STORZ PDD System and the drug Cysview®.

WARNING: Physicians who have red/green color blindness should not attempt to use the KARL STORZ D-Light C PDD System, because they will not be able to accurately judge the colors associated with normal and abnormal bladder tissue.

WARNING: The KARL STORZ PDD System is restricted to use only by physicians who have completed appropriate training in rigid cystoscopy, and who have been trained in the use of the KARL STORZ PDD System and the drug Cysview®. The physician should use his/her judgment and experience in interpreting the fluorescence images.

WARNING: Do not use the PDD mode or blue light mode if there is significant amounts of blood present, blood interferes with the emission of fluorescent images.

WARNING: Urine present in the bladder also interferes with the emission of fluorescent images. Be sure that the bladder has been emptied of urine and refilled with a clear fluid.

WARNING: Care must be exercised during endoscopic procedures. The instruments may be broken and the surrounding tissue may be damaged. Possible injuries may include perforation, infection, and electrical or thermal burns.

WARNING: The Hopkins II PDD telescopes and fluid light cables are supplied NON-STERILE. The scopes and accessories must be cleaned and sterilized prior to use and reuse. Please refer to the appropriate instruction manual for cleaning and sterilization instructions.

Safety Warnings and Precautions at the Facility Installation Site

WARNING: Do not use the PDD System in the presence of flammable anesthetics or fluids. There is a risk of explosion.

WARNING: The PDD System may only be used with accessories that have been designated by KARL STORZ as suitable for use with the system.

WARNING: Keep out of the reach of patients.

WARNING: DO NOT open the D-light-C or the PDD Camera unit; there is a risk of electrical shock. Refer servicing of the unit to qualified personnel. Removal of the instrument's cover by unauthorized personnel will VOID the manufacturer's warranty for the product.

WARNING: Connect the light source and camera systems to properly grounded "Hospital Use" or "Hospital Grade" electrical outlets. Check ground continuity regularly. Routinely inspect the power cords and the plugs. DO NOT use the power cords if either the cords or the plugs are damaged. Check ground continuity regularly.

WARNING: Check the PDD System for proper operation prior to each and every procedure.

Caution: Before connecting the unit to the electrical supply, verify that the line voltage stated on the instrument's identification plate is the same as the electrical supply to be used.

Caution: Use only fuses with the correct rating.

Caution: Unauthorized conversions or modifications of the unit will VOID the warranty and compromise the safety of the unit.

Caution: Do not allow any cleaning fluid to get into the system.

Cysview WARNINGS AND PRECAUTIONS

Anaphylaxis- Anaphylaxis, including anaphylactoid shock, has been reported following administration of Cysview. Prior to and during use of the Cysview, have trained personnel and therapies available for the treatment of anaphylaxis. The safety of repetitive Cysview exposures has not been evaluated.

Adverse Reactions- Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Anaphylactoid shock, hypersensitivity reactions, bladder pain, cystitis and abnormal urinalysis have been reported during post-marketing use of Cysview.

See the Cysview Package Insert for details for full prescribing information including, but not limited to, the clinical trials, clinical pharmacology, pharmacology, dosing and administration.

Installation

Inspection before Use

Note: Carefully read the instruction manual for each individual component of the PDD System (PDD Telescopes, D-light-C light source, Telecam® SL/Tricam® SL PDD) prior to use of this system for complete operating and maintenance instructions.

Note: Refer to the "Installation and/or Operation" section of each instruction manual for instructions on installing and operating each component.

Note: Refer to the "Inspection before Use" section of each instruction manual before installing the system.

Connecting the PDD SYSTEM components

1. Connect the camera control unit (CCU) of the Telecam® or Tricam® video camera to the video monitor using a RGB or S-VHS connecting cable.
2. If using a VCR, connect the CCU to the VCR using a RGB or S-VHS connecting cable. Use one of the cables to connect the VCR to the monitor.
3. Connect the D-light-C unit to the camera CCU using the SCB cable.
4. If using the optional keyboard, plug the keyboard connecting cable into the "Keyboard IN" socket on the CCU.
5. Plug the power cords of the D-light-C and CCU into properly grounded "Hospital Grade" or "Hospital Use" electrical outlets.
6. Plug the PDD camera head connector into the receptacle on the front of the CCU.
7. Attach the PDD camera head to the eyepiece of the PDD telescope by squeezing the levers on the coupler together. Ensure that the PDD camera head is securely attached.
8. Insert the closed end of the fluid light cable into the light socket on the D-light-C unit until it clicks.
9. Connect the open end of the fluid light cable to the light post on the PDD telescope.
10. Turn on the D-Light-C.
11. When the power is turned "on", the D-light-C light source will automatically be in the MANUAL operating mode and will default to the attenuated white light operating mode (Mode 1). Adjust the brightness of the light by using the ± keys on the -C light source to 100%. The current brightness level is shown on the bar display and the digital display (see D-light-C manual).

12. Turn on the Telecam® or Tricam® camera, video monitor, and VCR. Turning on the CCU automatically synchronizes the camera and the D-Light-C. Pressing a button on the front of the D-Light-C after the camera is turned on un-synchronizes the system. Use the buttons on the camera head or the footswitch to control the system.
13. Perform the white balancing procedures (in attenuated WL mode only)
 - a. Point the PDD cystoscope at a white surface and press the automatic white balance button on the front of the CCU (see Telecam® SL or Tricam® SL manual).OR
 - b. Point the PDD cystoscope at a white surface and press the blue button on the PDD camera head for 2 to 3 seconds.

Note: The camera and D-light-C always initialize in the attenuated white light mode (Mode 1) when first switched on.

Operating Instructions

Controlling the PDD System

Note: Always use the D-light-C in "MANUAL operating mode" when it is connected to the PDD camera head.

Note: Do not use the light mode button on the D-light-C unit to switch light modes. The PDD system will become unsynchronized. Use the buttons on the PDD camera head.

Once the components are connected, the Telecam® /Tricam® PDD camera head is automatically synchronized to control the light modes of the D-light-C light source. Some instructions for use of the camera head buttons are included below. Please refer to the PDD Camera head Instruction Card or the CCU manual for detailed instructions for use.

Selection of operating modes for fluorescence excitation

WARNING: The physician should first perform a complete cystoscopy examination in attenuated WL (Mode 1), then switch the light mode to BL (blue light) (Mode 2) fluorescence and repeat the examination. The PDD or blue light mode may only be used in combination with the drug Cysview® or there will be no fluorescent images present.

Using the PDD Camera Head Buttons

Active operating mode: BL (C) blue light (Mode 2)

Press the blue button on the PDD camera head for less than 1 second to switch the camera and the D-light-C light source to PDD blue light mode (Mode 2) from the attenuated WL mode (Mode 1).

Active operating mode: WL (W) white light (mode 1)

To return to attenuated WL mode, press the blue button again for less than 1 second to switch the camera and the D-light-C light source.

Note: Do not press the blue button for longer than 1 second or the PDD system will go into white balance mode.

Note: Operating Mode 3 on the D-Light (High intensity white light) cannot be accessed using the buttons on the camera head.

Changing the basic brightness (GAIN):

Press the silver button on the PDD camera head for less than 1 second to display the current gain setting on the monitor. Gain can be accessed using the silver button in either WL mode or PDD blue light mode. To decrease or increase the image brightness, briefly press the silver button to sequentially scroll through the gain settings until the image on the monitor is of desired quality.

The default gain setting in the attenuated WL mode is MEDIUM.
The default gain setting in the PDD or blue light mode is HIGH.

Note: Setting the gain to LOW in attenuated WL mode may result in clearer images than a setting of MEDIUM or HIGH.

Note: Do not press the silver button for longer than 1 second.

Using the Footswitch

Note: The footswitch may only be used with SCB compatible D-Light-C units and CCU's.

Active operating mode: PDD Blue light

To switch from attenuated WL to blue light mode, press the footswitch pedal one time.

Active operating mode: attenuated WL

To return to attenuated WL mode, press the footswitch pedal again.

Note: Operating mode 3 (high intensity white light) cannot be accessed using the footswitch.

USING THE KEYBOARD

The Telecam® SL and/or Tricam® SL camera allows the use of a keyboard to activate various camera functions including color test pattern and enhancement control.

Note: Refer to the Telecam® SL or Tricam® SL instruction manual or the PDD camera head Instruction Card for detailed instructions on the full range of functions available using the keyboard.

Color test pattern

Press the {F5} key to display a color test pattern on the monitor.
Press the {F5} key again to make it disappear.

Changing the digital image enhancement setting

Digital enhancement is available on Tricam® or Telecam® SL cameras that include an optional Image Processing Module (IPM). The enhancement option allows for maximum control or definition in the endoscopic image by choosing the preferred level of contrast and detail.

Press the {F10} key once to display the current enhancement setting on the monitor. While the display is present, press the {F10} key again to sequentially scroll through the various enhancement settings. To continuously display the current enhancement setting, press the {ALT} and {F10} key simultaneously. Press {ALT} and {F10} once more to make it disappear.

PDD System Trouble Shooting Guidelines

If the image is too dark:

- Check to be sure that D-Light-C unit and camera are connected with the SCB cable. Be sure that the camera and the D-Light-C are synchronized. If the buttons on the D-Light-C have been used after plugging in the camera, the system may not be synchronized. To synchronize the systems turn off both the CCU and the D-Light-C. Turn on the D-Light-C first and then the turn on the CCU. The system will be synchronized. The CCU controls the filters on the D-Light-C.
- Check to ensure that the SCB cable is connected correctly.
- Be sure that the endoscope is in good condition and that all optical surfaces are clean.
- The default shutter speed in the PDD System is 1/15 second. Shutter speed can be adjusted by pressing the silver button on the camera head for more than 3 seconds. Shutter speeds of 1/15 second or 1/30 second are recommended for the PDD or blue light mode. Refer to the PDD camera head instruction card for detailed information.
- If using a PDD beamsplitter camera head, check the observer port to be sure that it is closed and no room light is entering the camera through the port. Close the port with a clip that comes with the camera or cover the port with your thumb.

Check Cystoscopy procedural issues:

- Move the cystoscope closer to the bladder wall once a suspicious lesion is located as this may improve the intensity of the image.
- Reduce any **blood** in the bladder. Blood interferes with the emission of fluorescent images.
- Empty the bladder before the procedure and refill it with clear fluid. Urine in the bladder interferes with the emission of fluorescent images and reduces appearance of the blue background. The blue light image will be foggy. The image may also appear yellowish or greenish.

If the image is bright but foggy:

- Ensure that the monitor settings are in the neutral position
- Check to make sure that there are no floating particles in the bladder. Drain the bladder and refill it completely
- Empty the bladder before the procedure and refill it with clear fluid. The effect of too much urine in the bladder interferes with the emission of fluorescent images and reduces appearance of the blue background. Therefore, the blue light image is typically bright but very foggy. The image may also appear yellowish or greenish.

If tumors are not red:

- Check to be sure that the drug (CYSVIEW[®]) instillation was performed correctly. There should always be red fluorescence on the bladder neck. Red fluorescence in the bladder neck is a sign that the drug was applied properly. **This is not a tumor and should not be resected!!**
- Empty the bladder before the procedure and refill it with clear fluid. The effect of too much urine in the bladder interferes with the emission of fluorescent images and reduces appearance of the blue background. Therefore, the blue light image is typically bright but very foggy. The image may also appear yellowish or greenish.

If the white light image is unclear:

- Be sure that there is no endoscope damage by carefully checking the white light image.

- Check that all optical surfaces on the endoscope are clean
- Setting the GAIN to "LOW" gives clearer images in white light mode than settings of medium or high.

If all of the above remedies do not result in an improvement to the image:

Look through the observer port on the beam splitter camera head with the naked eye.

- If a good image is present when looking with the naked eye then there is a problem with the camera
- If the image is too dark, then there is a procedure-related problem or a problem related to the D-Light-C, light cable or telescope. Change the light cable first and determine if the problem is solved.

Document the endoscopic image and forward it to KARL STORZ. Contact KARL STORZ Technical Support at (800) 421-0837 for help with troubleshooting.

Technical Specifications

Technical documentation

Upon request, the manufacturer will provide those circuit diagrams, itemized parts listings, descriptions, sets of adjustment instructions and other items of available documentation to suitably qualified user personnel duly authorized by the manufacturer for their use in repairing those components of the instrument that have been designated as repairable by their respective manufacturers.

Supply of such technical documentation relating to the instrument shall not be construed as constituting manufacturer's authorization of user's personnel, regardless of their levels of technical training, to open or repair the instrument.

Explicitly exempted here from are those maintenance and repair operations described in this manual.

KARL STORZ reserves the right to make engineering modifications in the interest of promoting technological progress and generating performance improvements without the obligation on our part to submit prior notice thereof.

Maintenance Operations

Performance of regular maintenance is not essential. However, regular maintenance can contribute to identifying problems before they become serious, thus enhancing the instrument's reliability and extending its useful operating life. Maintenance services can be obtained from Karl Storz Endoscopy-America, Inc.

Servicing and repair

Defective equipment must be serviced and repaired exclusively by persons authorized by KARL STORZ; all repair work must employ original KARL STORZ parts. Opening of the instrument or performance of any repairs or modifications of the instrument by unauthorized personnel will void the warranty.

THOROUGHLY INSPECT SHIPMENT IMMEDIATELY UPON ARRIVAL.

Shipping

Although all Kari Storz products are carefully packed to minimize in-transit damage, all shipments should be carefully examined upon receipt.

1. If a product is damaged, Customer must promptly document the nature and extent of the damage and contact the carrier.
2. If concealed loss or damage is discovered, Customer must retain all packing materials and immediately notify the carrier, requesting an inspection. This is essential and must be done within seven (7) days of delivery.
3. If shipments are received short, Customer must contact the carrier and KSEA's Customer Service Department at once.

KSEA reserves the right to make partial shipments on any Order. Invoice(s) for partial shipments are payable upon receipt.

RETURN POLICY

A return merchandise authorization, in the form of a Sales Order ("SO #") or a Return Delivery ("RD #") must be obtained from KSEA's Customer Service Department prior to returning any products. When phoning or writing for such a return merchandise authorization, the Customer Service Representative must be provided with:

- (1) Customer name and number, as it appears on the invoice;
- (2) the telephone number and the person to contact;
- (3) the applicable P.O. number;
- (4) the Karl Storz catalog number and, if applicable, the serial number for each product; and,
- (5) the reason for the return.

KSEA reserves the right to refuse or return (collect) any products sent back to KSEA without prior authorization of its Customer Service Department. Returns must be shipped pre-paid to KSEA, ATTN: SO# or RD#. KSEA's Customer Service Department will provide the return address and a SO# or RD#. Shipping charges will be reimbursed if the return was due to an error on the part of KSEA.

When returning products, Customer should include a copy of the original invoice or packing slip to ensure prompt issuing of credit.

Full credit will only be issued for products that are returned within 30 days of invoice date, and so long as such items are unused, in resaleable condition, and in the original, as well as undamaged, packaging.

All products returned after 30 days from the date of invoice are subject to a 15% restocking fee.

If the returned product requires refurbishing or repacking, and is accepted for credit, a service charge will be deducted from the amount of credit.

The following products may not be returned for credit or exchanged:

- (1) products held longer than 90 days from invoice date;
- (2) sterile packaged products;
- (3) discontinued products;
- (4) instruments that are etched or engraved by Customer;
- (5) used instruments not in their original packaging;
- (6) products damaged by the Customer; and,
- (7) products purchased "as is" or as demo products.

In order to prevent the transmission of disease to the medical facilities' and/or KSEA's personnel, all products must be cleaned and then sterilized and/or disinfected before sending such products back to KSEA, who reserves the right to return contaminated products to the Customer or to charge a "cleaning fee" to handle such products. Additionally, if any product becomes damaged and is not immediately returned, KSEA assumes no responsibility or liability for Customer's continued use of that damaged product. KSEA

does not guarantee the performance, and may decline to repair or accept for repair/exchange, any product that has been repaired, modified and/or altered by any person or entity other than KSEA or an authorized repair facility of KSEA.

REPAIR PROGRAM

If repairs become necessary, for other than damages incurred during initial shipment (see "Shipping" above); Customer must alert KSEA of the reason why Customer will be returning the product, and then carefully repack and ship the damaged product (freight prepaid) to KSEA, in accordance with KSEA's "Repair/Exchange Policy," set forth below. Customer should describe, in writing, the damage and the apparent problem, along with the name of the person(s), who KSEA should contact to discuss the problem, the address of the facility and the telephone number. Warranty repairs will be made without charge (see "Warranty Policy" for covered repairs). All other repairs are subject to KSEA's standard repair charges. If requested, Customer will be advised of the estimated cost of the repair work before it is undertaken.

REPAIR/EXCHANGE POLICY

KSEA maintains an extensive inventory of refurbished products, which is generally large enough to ensure prompt replacements for most damaged products which are deemed to be economically "refurbishable" or "repairable." In the event a damaged product is determined to be "not economic to repair" ("NER"), by a KSEA technician, there will be an additional charge to Customer. All repaired and refurbished products carry the applicable Karl Storz warranty. Upon Ordering a repair/exchange product, the Customer must first obtain an SO# or RD# from KSEA's Customer Service Department and then return the damaged product to KSEA. When phoning or writing for an SO # or RD#, Customer must follow the five (5) step return procedure set forth in KSEA's "Return Policy" noted above. If the damaged product is not returned within thirty (30) days of receipt of the replacement product, Customer will be invoiced for any additional charges. KSEA reserves the right to refuse or return (collect) any product sent back without prior authorization of KSEA's Customer Service Department. Returns must be shipped pre-paid to KSEA, attention SO # or RD#. If an exchange is not in stock, KSEA assumes no responsibility for loss or damage resulting from its unavailability or untimely delivery. Products that are etched and/or engraved by a Customer, as well as used products not in their original and undamaged packaging, cannot be exchanged.

WARRANTY POLICY

Except as otherwise provided herein and/or by the applicable warranty information for a specific product or type of product, all Karl Storz branded products are generally warranted to be free from defects in workmanship and materials for one (1) year from date of sale. However, since some products carry a longer or shorter warranty period, Customer should check all product specific literature for the exact warranty period. Any such products with a defect, occurring during the applicable warranty period, will be promptly replaced, or at the discretion of KSEA, repaired, at no charge to the Customer. KSEA is not liable, directly or by way of indemnity, either expressly or impliedly, for any damages which might arise or be caused, whether by the Customer or by any of the users of the products, as a result of, connected with, to the extent of or otherwise attributable to: misuse, mishandling and/or improper operation; repairs, servicing, modifications or alterations performed by any person or entity, other than KSEA or an authorized repair facility of KSEA; use in combination with adaptors and/or equipment from other manufacturers or, use in any manner or in a medical procedure, other than those for which such product is labeled, designed and is otherwise intended to be used; and, Any special, incidental, consequential, punitive, exemplary or other damages, including but not limited to alleged damages for delayed shipment, product failure, product design or production, for loss of future business, or from any other cause, whatsoever, whether based on breach of contract, warranty, tort, strict or products liability, infringement of patents, trade secrets, trademarks, copyrights, or other proprietary rights or legal theory, in connection with or arising from the purchase, sale, lease, rental, installation or use of such Karl Storz products or with respect to the within terms and conditions.

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Appendices

Appendix 1: Rigid Hopkins II PDD Telescopes Instruction Manual

Appendix 2: D-Light-C Light Source Instruction Manual

Appendix 3: PDD Camera Head Instruction Card

Appendix 4: Telecam® SL PAL/NTSC Instruction Manual

Appendix 5: Tricam® SL PAL/NTSC Instruction Manual

Appendix 6: Fluid Light Cable Package Insert